

**WHAT IS CLAIMED IS:**

1. A method of evaluating the efficiency of a sterilization process, which comprises the steps of:
  - a) subjecting a sufficient amount of at least one prion protein degradation indicator in a container to said sterilization process; and
  - b) determining the level of degradation of said indicator.
2. The method according to claim 1, wherein said indicator of step a) is transcribed by a gene naturally occurring in a fungus.
3. The method according to claim 2, wherein said fungus is selected from the group consisting of *Saccharomyces cerevisiae*, and *Podospora anserina*.
4. The method according to claim 3, wherein said indicator is transcribed by a gene selected from the group consisting of SUP35, URE2, and HET-s.
5. The method according to claim 2, wherein said indicator is selected from the group consisting of Sup35p, Ure2p, Het-s protein, and combination thereof.
6. The method according to claims 1 to 5, wherein said indicator is a purified form naturally occurring in *Saccharomyces cerevisiae*, *Podospora anserina* or a fungus, a recombinant form, an analog, a mutant, or a fragment of said indicator.

7. The method according to claim 1 to 5, wherein said indicator is a biological indicator, a biochemical indicator, or a chemical indicator.

8. The method according to claim 1, wherein step b) is performed by determining the weight or the mass, quantifying radicals, colorimetric variations, radiometry, nephelometry, immuno-enzymatic method, Western blotting, dot blotting, radioimmuno assay, circular dichroism, electron microscopy, fluorescent microscopy, FTIR, Congo red binding, or proteinase digestion.

9. The method according to claim 1, wherein said sterilization process is performed by autoclaving, chemical exposure, dry heating, low temperature plasma gas, ozone-based exposure, or sterilization techniques using alkylant and/or oxidizing sterilizing agents.

10. The method according to claim 9, wherein said chemical exposure is a vapor or a solution selected from the group consisting of detergent, ethylene oxide, protease, sodium hydroxide, and enzyme.

11. The method of claim 1, wherein said amount of indicator of step a) is between 0.1 ng to 100 g.

12. The method of claim 1, wherein said container is of a material selected from the group consisting of paper, glass, borosilicate, metal, polymer, alloy, and composite.

- 19 -

13. The method according to claim 11, wherein said container is porous, permeable, or semi-permeable.